

DENAGARD - tiamulin fumarate solution, concentrate
Novartis Animal Health US, Inc.

Denagard®

(tiamulin)

Liquid Concentrate

12.3% Tiamulin hydrogen fumarate

NADA 140-916, Approved by FDA

One Quart

(32fl oz; 946mL)

WARNING:

Keep out of reach of children. Avoid direct contact with the skin. Direct contact with skin or mucous membranes may cause irritation.

Withdraw medicated water 3 days before slaughter after use at 3.5 mg per pound and 7 days before slaughter after use at 10.5 mg per pound.

ACTIVE INGREDIENT:

This bottle contains 4.10 oz (116.4 g) tiamulin hydrogen fumarate in solution.

CAUTION:

For use in animals only – Not for human use.

Prepare fresh medicated water daily. Use as the only source of drinking water for 5 days. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined.

CONTRAINDICATION:

Swine being treated with Denagard (tiamulin) should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.

INDICATIONS:

Treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae*, susceptible to tiamulin.

USE DIRECTIONS:

Do not use undiluted.

This bottle contains 116,400 mg tiamulin hydrogen fumarate for use in preparing medicated drinking water for swine. See package insert for complete directions, read completely.

Protect from direct sunlight. Store at controlled room temperature, 59°-86°F (15°-30°C).

Restricted Drug (California): Use only as directed

Denagard® is a registered trademark of Novartis AG

U.S. Patent No. 4,278,674

Product # 701

NAH/DEN-LC/BL/2

Marketed by:

Novartis Animal Health US, Inc.

Greensboro, NC 27408 U.S.A.

NADA 140-916, Approved by FDA

Denagard®

(tiamulin)

Liquid Concentrate

DESCRIPTION:

Denagard (tiamulin) Liquid Concentrate is a solution containing 12.3% tiamulin hydrogen fumarate (w/v) in an aqueous solution. The active ingredient, tiamulin, chemically is 14-desoxy-14-[(2-diethylaminoethyl) mercaptoacetoxy] mutilin hydrogen fumarate, a semi-synthetic diterpene antibiotic. Denagard Liquid Concentrate is for use only in preparing medicated drinking water for swine.

ACTIONS:

Tiamulin is active against *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* and *Actinobacillus pleuropneumoniae*. It is readily absorbed from the gut and can be found in the blood within 30 minutes after dosing.

INDICATIONS:

Denagard (tiamulin), when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

CONTRAINDICATIONS:

Swine being treated with Denagard (tiamulin) should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.

WARNING:

Keep out of reach of children. Avoid contact with skin. Direct contact with skin or mucous membranes may cause irritation. Withdraw medicated water 3 days before slaughter after treatment at 3.5 mg per pound and 7 days before slaughter following treatment at 10.5 mg per pound body weight.

CAUTION:

For use in drinking water of swine only. Prepare fresh medicated water daily. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined. For animal use only – not for use in humans.

ADVERSE REACTIONS:

Overdoses of Denagard have sometimes produced transitory salivation, vomiting and an apparent calming effect on the pig. If signs of toxicity occur, discontinue use of medicated water and replace with clean, fresh water.

In rare cases, redness of the skin primarily over the ham and underline has been observed during medication. If these signs appear, discontinue use of this drug. Provide ample clean drinking water. Thoroughly rinse (hose down) the housing to remove urine and feces from animal contact surfaces or move the animals to clean pens. If the condition persists, consult your veterinarian.

Studies to evaluate the safety of the water soluble form of tiamulin in breeding swine have not been done.

USE DIRECTIONS:

The concentration of tiamulin in the drinking water must be adjusted to compensate for variation in water consumption due to weight or size of the pig, environmental temperature and other factors. It is important that pigs receive the proper drug dose, 3.5 mg tiamulin hydrogen fumarate per pound for swine dysentery or 10.5 mg tiamulin hydrogen fumarate per pound for swine pneumonia, each day for 5 consecutive days.

Table 1 Approximate daily water consumption per pig.

Pig Weight, lb	Water Intake, gal.	Pig Weight, lb	Water Intake, gal.
20	0.3 - 0.5	125	1.0 – 2.0
45	0.4 – 1.1	180	1.2 – 3.0
75	0.7 – 1.5		

Note:

1. Prepare fresh medicated drinking water every day for the 5 day treatment period.
2. Water medicated with Denagard should be the only source of drinking water during the treatment period.

Directions for preparing Denagard medicated solutions: Determine the amount of Denagard Liquid Concentrate needed to medicate the desired volume of drinking water at the proper concentration. Carefully measure out this amount, add it to the water and stir to thoroughly mix.

Table 2 Denagard Liquid Concentrate

		One Quart	
Net tiamulin hydrogen fumarate content:		116,400 mg	
Diseases to be treated:		Swine Dysentery	Swine Pneumonia
Daily tiamulin hydrogen fumarate required per pound body weight:		3.5 mg	10.5 mg
Required treatment duration:		5 days	5 days
Pig body weight this bottle will treat for ONE day:		33,257 lb	11,086 lb
Number of pigs this bottle will treat for ONE day:		Pig Wt, lb	
		20	554
		1,663	

	45	739	246
	75	443	148
	125	266	88
	180	185	62
Suggested final dilution of:	1 bottle	512 gal	-
	3 bottles	-	512 gal
	½ pint (8 oz)	128 gal	43 gal
	1½ pints (24 oz)	-	128 gal
Tiamulin hydrogen fumarate concentration per gallon at suggested final dilution*	227 mg (60 ppm)	681 mg (180 ppm)	

***Note:** Increase or decrease dilution rate as required to obtain proper daily drug dose.

Directions for using Denagard in medicated proportioners: One quart of Denagard Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide 227 mg of tiamulin hydrogen fumarate per gallon to 512 gallons of drinking water for treatment of swine dysentery. Three quarts of Denagard Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide 681 mg tiamulin hydrogen fumarate per gallon to a total of 512 gallons of drinking water for treatment of swine pneumonia.

One pint of Denagard Liquid Concentrate mixed with water to make two gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide 227 mg of tiamulin hydrogen fumarate per gallon to 256 gallons of drinking water for treatment of swine dysentery. Use three pints of Denagard Liquid Concentrate in two gallons of stock solution to be metered at one fluid ounce per gallon to deliver 681 mg per gallon to a total of 256 gallons of drinking water for treatment of swine pneumonia. One-half pint (8 fluid ounces) of Denagard Liquid Concentrate diluted with water to make one gallon of stock solution and this stock solution metered at one fluid ounce of drinking water with a medication proportioner will provide 227 mg of tiamulin hydrogen fumarate per gallon to 128 gallons of drinking water for treatment of swine dysentery.

Use one and one-half pints of Denagard Liquid Concentrate per gallon of stock solution to be metered at one fluid ounce per gallon to provide 681 mg per gallon to 128 gallons of drinking water for treatment of swine pneumonia.

In barrels or tanks: Three fluid ounces of Denagard Liquid Concentrate will medicate 48 gallons of drinking water at 227 mg per gallon for treatment of swine dysentery or 16 gallons at 681 mg per gallon for treatment of swine pneumonia.

Measure Denagard Liquid concentrate carefully, pour into the proper amount of water and thoroughly mix. The concentration of tiamulin hydrogen fumarate in the stock solution and in the drinking water delivered must be adjusted to compensate for variation in water consumption by pigs due to body weight, environmental and other factors. It is important that the pigs receive the proper drug dose of 3.5 mg of tiamulin hydrogen fumarate per pound of body weight daily for 5 consecutive days for treatment of swine dysentery or a dose of 10.5 mg per pound body weight daily for 5 consecutive days for treatment of swine pneumonia.

Attention: If no response to treatment is obtained within 5 days re-establish the diagnosis. Failure of response may be related to the presence of non-susceptible organisms or other complicating disease conditions. Because of the tendency for the disease to recur on premises with a history of swine dysentery or with swine pneumonia, a control program should be implemented after treatment. Drugs are not substitutes for proper sanitary measures or good management, but should be used in conjunction with such practices.

HOW SUPPLIED:

Container Size	Active Ingredients
Quart bottles (32 fl oz; 946 mL)	12.3% (116.4g) Tiamulin hydrogen fumarate

Protect from direct sunlight. Store at controlled room temperature, 59°-86°F (15°-30°C).

Observe expiration date.

U.S. Patent No. 4,278,674


PRINCIPAL DISPLAY PANEL

Denagard®
(tiamulin)
Liquid Concentrate
12.3% Tiamulin
hydrogen fumarate
NADA 140-916,
Approved by FDA
One Quart
(32 fl oz; 946 mL)
NOVARTIS

Exp. Date:

Lot No.:

↑ TEAR HERE



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NOVARTIS

ANIMAL HEALTH

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Indications: Treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae*, susceptible to tiamulin.

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Greensboro, NC 27408 U.S.A.

Pat. 4488322

CCP / Fix-a-Farm

